HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M224111

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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December 18, 1998

WARNING LETTER
CIN-WL-99-057

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John E. Trybuski, President
Scottcare Corporation, Inc.
4971 West 150th Street
Cleveland, OH 44135

Dear Mr. Trybuski:

On November 2 – 5 and 9, 1998, the Food and Drug Administration (FDA) conducted an inspection of your firm which manufacturers the Tele-Rehab II Cardiopulmonary Monitoring System. The cardiac monitor is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The investigator found deviations from the Quality System Regulation, Good Manufacturing Practice (GMP) for Medical Devices as listed in Part 820 of Title 21, Code of Federal Regulations (CFR). This causes the Tele-Rehab II Cardiopulmonary Monitoring System to be adulterated within the meaning of Section 501 (h) of the Act, in that the methods used in or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Quality System Regulation. Part 820.

The following deviations from the Device Quality System Regulations were documented:

1. Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation, as required by 21 CFR 820.30(b).

2. Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient; failure to document, review and approve, by an authorized individual, the design input requirements, as required by 21 CFR 820.30(c) . For example:

    a. The firm has not established or implemented a written procedure for the identification and control of design input which includes potential design inputs relating to intended use, safety, risk analysis, human factors, reliability, limits and tolerances, voluntary standards, and manufacturing processes.

    b. Requirement specifications do not exist for the current version of software.

3. Failure to establish and maintain procedures for defining and documenting design output, as required by 21 CFR 820.30(d).

4. Failure to establish and maintain procedures for verifying the device design; failure to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f). For example:

    There is no documented written protocol describing the testing of the software for the current versions of software. Furthermore, there is no documentation showing testing was conducted.

5. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e).

6. Failure to establish and maintain procedures for the identification, documentation, validation/ verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:

   There is no formal change control process for software changes for the current version of software.

7. Failure to establish and maintain a Device History File for each type of device, failure of the file to contain or reference the records necessary to demonstrate the design was developed in accordance with the approved design plan, as required by 21 CFR 820.30(j).

8. Failure to establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100(a) for design control procedures.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within fifteen days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,

Charles W. Sedgwick
Acting District Director
Cincinnati District

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